

Agricultural Research Service, USDA

§ 550.18

(2) Total in-house costs to the REE Agency. (Direct and indirect costs)

(3) Total in-house costs to the Cooperator. (Direct and indirect costs)

§ 550.17 Peer review.

Upon request of the REE Agency, co-operators may be requested to provide documentation in support of peer review activities and cooperator personnel may be requested to participate in peer review forums to assist the REE Agency in their reviews.

§ 550.18 Assurances/certifications.

(a) Governmentwide Debarment and Suspension (Non procurement)—7 CFR 3017;

(b) Governmentwide requirements for Drug-Free Workplace—7 CFR 3021;

(c) *Non-discrimination.* The Cooperator assures compliance with the following requirement: No person in the United States shall, on the grounds of race, color, national origin, sex, age, religion, political beliefs, or disability, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any project or activity under a non-assistance cooperative agreement.

(d) *Protection of human subjects requirements.* The Cooperator assures compliance with the following provisions regarding the rights and welfare of human subjects:

(1) The Cooperator is responsible for safeguarding the rights and welfare of any human subjects involved in research, development, and related activities supported by this Agreement. The Cooperator may conduct research involving human subjects only as prescribed in the statement of work and as approved by the Cooperator's Cognizant Institutional Review Board. Prior to conducting such research, the Cooperator shall obtain and document a legally sufficient informed consent from each human subject involved. No such informed consent shall include any exculpatory language through which the subject is made to waive, or to appear to waive, any of his or her legal rights, including any release of the Cooperator or its agents from liability for negligence.

(2) The Cooperator agrees to comply with U.S. Department of Health and

Human Services' regulations regarding human subjects, appearing in 45 CFR part 46 (as amended).

(3) It will comply with REE policy, which is to assure that the risks do not outweigh either potential benefits to the subjects or the expected value of the knowledge sought.

(4) Selection of subject or groups of subjects shall be made without regard to sex, race, color, religion, or national origin unless these characteristics are factors to be studied.

(e) *Animal Welfare Act requirements.* The Cooperator assures compliance with the Animal Welfare Act, as amended, 7 U.S.C. 2131, *et seq.*, and the regulations promulgated thereunder by the Secretary of Agriculture (9 CFR, subchapter A) pertaining to the care, handling, and treatment of warm-blooded animals held or used for research, teaching, or other activities supported by Federal funds. The Cooperator may request registration of facilities and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the Region in which their facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this requirement, may be obtained by contacting the Senior Staff Officer, Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

(f) *Recombinant DNA research requirements.* The Cooperator assures that it will assume primary responsibility for implementing proper conduct on recombinant DNA research and it will comply with the National Institute of Health Guidelines for Recombinant DNA Research, as revised.

(1) If the Cooperator wishes to send or receive registered recombinant DNA material which is subject to quarantine laws, permits to transfer this material into the U.S. or across state lines may be obtained by contacting USDA/APHIS/PPQ, Scientific Services—Biotechnology Permits, 4700 River Road, Unit 133, Riverdale, Maryland 20737. In the event that the Cooperator has not established the necessary biosafety committee, a request for guidance or assistance may be made to the USDA Recombinant DNA Research Officer.